

# EXHIBIT 1

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
Washington, D.C.**

**Before the Honorable Clark S. Cheney  
Administrative Law Judge**

**In the Matter of**

**CERTAIN PRE-FILLED SYRINGES  
FOR INTRAVITREAL INJECTION  
AND COMPONENTS THEREOF**

Investigation No. 337-TA-1207

**COMPLAINANTS' UNOPPOSED MOTION TO TERMINATE THE INVESTIGATION  
IN ITS ENTIRETY BASED ON WITHDRAWAL OF COMPLAINT AND REQUEST FOR  
EXPEDITED TREATMENT (MOTION No. 1207-031)**

**I. GROUND RULE 5.1 CERTIFICATION**

Complainants Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, “Novartis”) certifies that it has met and conferred with Respondent Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Commission Investigative Staff (“Staff”) prior to filing this Motion. Regeneron and Staff do not oppose.

**II. INTRODUCTION**

Pursuant to Commission Rule 210.21(a)(1), 19 C.F.R. § 210.21(a)(1), and Ground Rule 5.8, Novartis respectfully moves to terminate the Investigation in its entirety based on withdrawal of the Complaint. To conserve substantial resources of the private parties, the Staff, and the Administrative Law Judge, and with the hearing approaching in less than two weeks, Novartis requests expedited treatment of this Motion.

### **III. DISCUSSION**

Novartis has made clear since it filed its Complaint that it does not want a single patient to be deprived of any necessary treatment resulting from the Commission's issuance of any remedy in this Investigation. Indeed, as Novartis stated in its prehearing brief:

Novartis stands by its continued commitment to patients and wholeheartedly agrees that a remedial order should not jeopardize patients' access to appropriate treatments. Here, because there is no credible evidence that such a risk exists here, [] an exclusion order should issue. If the Commission has any credible doubt on that score, it should use its broad and flexible remedial powers to fashion a remedy that protects the public interest, incentivizes Regeneron to convert EYLEA back to the non-infringing vial presentation. The Commission should not permit Regeneron to reap profits from its continued flaunting of Novartis's valid patent rights.

Novartis's Pre-Hr'g Br. at 6 (EDIS Doc. ID 736888); *see also* Novartis's Substitute Pre-Hr'g Br. at 6 (EDIS Doc. ID 737750). Novartis strongly believes it would prevail on the merits in this investigation—indeed, the Administrative Law Judge recently granted Novartis's motion for partial summary determination that Regeneron directly infringed U.S. Patent No. 9,220,631 (the "Asserted Patent") and that Novartis satisfied both the technical and economic prongs of the domestic industry requirement. *See* Order No. 31. Novartis maintains that the Asserted Patent is valid and that Regeneron cannot prove otherwise.

Novartis also believes that there are no public interest concerns that would justify tailoring any remedy that could issue in this Investigation. However, the Staff has suggested otherwise, advocating that the Commission should delay the implementation of any remedy by at least three years, if it issues one at all. Although Novartis disagrees with Staff, it takes seriously the concerns Staff noted in its pre-hearing brief. As a result, Novartis is withdrawing this Complaint and will, instead, pursue relief in district court.

Novartis submits this motion to terminate the Investigation should be granted. The Commission's rules permit "[a]ny party [to] move at any time prior to the issuance of an initial determination on violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, to terminate an investigation in whole or in part as to any or all respondents, on the basis of withdrawal of the complaint or certain allegations contained therein . . . ." 19 C.F.R. § 210.21(a)(1). "In the absence of extraordinary circumstances, termination of an investigation will be readily granted to a complainant during the prehearing stage of an investigation." *Certain Microfluidic Sys. & Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-1100, Order No. 27 at 1 (Dec. 10, 2018) (citing *Certain Television Sets, Television Receivers, Television Tuners, & Components Thereof*, Inv. No. 337-TA-910, Order No. 50 (Nov. 12, 2014)); *see also Certain Subsea Telecommunications Sys. & Components Thereof*, Inv. No. 337-TA-1098, Order No. 52 (Dec. 6, 2018); *Certain Memory Modules & Components Thereof*, Inv. No. 337-TA-1089, Order No. 27 at 2 (Dec. 6, 2018); *Certain Toner Cartridges & Components Thereof*, Inv. No. 337 TA-1106, Order No. 33 (Nov. 26, 2018). Here, the Administrative Law Judge has not yet issued his initial determination on violation. Indeed, the hearing is currently scheduled to begin in about two weeks. Furthermore, public policy supports termination of the withdrawn complaint in order to conserve public and private resources. *See Certain Modular LED Display Panels & Components Thereof*, Inv. No. 337-TA-1114, Order No. 23 at 2-3 (Oct. 24, 2018); *Certain Road Construction Machs. & Components Thereof*, Inv. No. 337-TA-1088, Order No. 38 (Oct. 16, 2018).

In addition, good cause exists to grant this motion to terminate and to grant an immediate stay of the procedural schedule pending a ruling from the Administrative Law Judge on Novartis's motion to terminate the Investigation.<sup>1</sup> *See, e.g., Certain Muzzle-Loading Firearms &*

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<sup>1</sup> Regeneron has also confirmed that it does not oppose a stay pending resolution of this motion.

*Components Thereof*, Inv. No. 337-TA-777, Order No. 24 at 2 (Nov. 30, 2011) (granting motion to suspend the procedural pending a ruling on a motion to terminate); *Certain Devices for Mobile Data Commc'n*, Inv. No. 337-TA-809, Order No. 60, at 2 (Oct. 12, 2012) (same); *Certain Coupler Devices for Power Supply Facilities, Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-590, Order No. 31 (Aug. 23, 2007) (same). The evidentiary hearing is scheduled to begin in less than two weeks. In the interim, responses to motions *in limine* are due and the parties will be engaging in significant evidentiary hearing preparation. It is unnecessary for the parties to continue to expend resources to litigate issues pending the outcome of Novartis's motion to terminate. The request for a stay and expedited treatment will therefore conserve the resources of the private parties, the Staff, and the Administrative Law Judge.

Pursuant to Commission Rule 210.21(a)(1), Novartis states that there are no agreements, written or oral, express or implied, by or between the private parties concerning the subject matter of this Investigation (*i.e.*, there are no settlement agreements, licenses, or any other such agreements). In addition, there are no extraordinary circumstances that would justify denying termination of this Investigation based on Novartis withdrawing the Complaint.

#### **IV. CONCLUSION**

Based on the foregoing, Novartis respectfully requests that this Investigation be terminated in its entirety based on withdrawal of the Complaint and requests an immediate stay of all procedural schedule deadlines pending final resolution of this Motion.

Dated: April 8, 2021

Respectfully submitted,

By: /s/ Elizabeth J. Holland

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**CERTIFICATE OF SERVICE**

I, Tessa Mager, hereby certify that on this 8th day of April, 2021, copies of the foregoing were served upon the following parties as indicated:

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